Stent misalignment of the Zenith Dissection Endovascular System

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The Zenith Dissection Endovascular System is a device designed for treatment of aortic type B dissection utilizing the Provisional ExTension to Induce COmplete ATtachment (PETTICOAT) technique. Due to the stent design (low radial force and lack of columnar support), significant risk of stent misalignment exists, which we have encountered in four out of 25 patients treated since 2005. Misalignment may result from excessive manipulation of the delivery system at the time of implantation or during catheter manipulation during adjunctive or secondary procedures. The manufacturer has modified the design of this device in order to prevent misalignment, although no serious clinical consequences of this misalignment have been reported with a mean follow-up of 50 months. Care with catheter manipulation after device deployment and accurate review of postoperative imaging are still warranted. (J Vasc Surg 2013;57:515-7.)

Self-expandable bare stents may be used to promote true lumen expansion and remodeling as an adjunctive to coverage of the proximal entry tear with a stent graft (Provisional ExTension to Induce COmplete ATtachment [PETTICOAT] technique) during endovascular treatment of type B aortic dissection (TBD).[1] The Zenith Dissection Endovascular System (ZDES; William Cook Europe, Bjaerverskov, Denmark) was specifically designed for this purpose and has demonstrated encouraging clinical results.[2-5] Since 2005, the device has been available as a custom manufactured device and, at present, is commercially distributed with the CE mark (indicates conformity with the essential requirements of applicable European Community directives regarding medical devices) obtained in July 2010.

Due to the stent design, which incorporates both low radial force and lack of columnar support, stent misalignment is a distinct possibility that has not been widely reported.

CASE REPORT

Since 1999, 459 thoracic aortic stent grafts have been placed for a variety of aortic pathologies (including 79 cases of TBD). Since 2005, we have employed the ZDES in 25 selected cases of TBD. Details of this cohort have been previously described.[5]

All of the procedures were performed in the operating room with a portable C-arm. All patients received a predischarge computed tomography (CT) scan and were followed with a CT scan performed at 6 months and yearly thereafter (mean, 35 ± 17 months). Scans were analyzed on a digital workstation (OsiriX software; Pixmeo SARL, Bernex, Switzerland) with multiplannar reconstructions.

In four cases, we observed misalignment of the bare stent, defined as a lack of complete adherence of the stent to the aortic wall (Fig 1). Notably, this behavior was detected intraoperatively only during the last case but was discovered in all cases at the time of predischarge CT scan. No late-onset cases of misalignment were noticed at follow-up. All these cases were recorded early in our experience.

These cases included three cases of acute or subacute and one case of chronic TBD with a collapsed true lumen. The anatomical characteristics of the aorta of these cases of stent misalignment did not differ from the other cases treated in our study. The median diameter of the landing zone was proximally 33 mm (range, 27 to 38 mm) and distally 10 mm (range, 7 to 13 mm) estimated based on true lumen diameter. The false lumen was fully patent in all cases. Moreover, the preoperative volumetric assessment of the true and false lumen also did not significantly differ from the other cases (mean preoperative true lumen volume of 91 cm^3 and false lumen of 310 cm^3). No adjunctive surgical procedures (ie, supra-aortic debranching) were required. A stent graft was used proximally in one patient. In two cases, two bare stents were used with an overlap of one stent between them.

In five of our 25 patients treated with ZEDS, an endovascular adjunctive procedure was performed, and two of these resulted in postoperative misalignment (one renal stent and one balloon-molding). No significative anatomic differences were observed in the other three cases with adjunctive procedures. In all cases, the completion angiography was performed through a catheter placed in the proximal aorta using contralateral femoral access. In the patient we detected intraoperatively, we decided to avoid any further manipulation due to the presence of the frail wall of the aortic dissection and because we did not observe any immediate flow or other clinical problem related to misalignment.

Notably, since the four cases of misalignment were detected, we started employing hydrophilic introducers and catheters during these procedures as well as undertaking more careful manipulation of the distal end of the bare metal stent. No additional cases have been observed.

At a mean follow-up of 49.6 ± 4.9 months for the four misaligned stent cases, no adverse clinical events have been observed or

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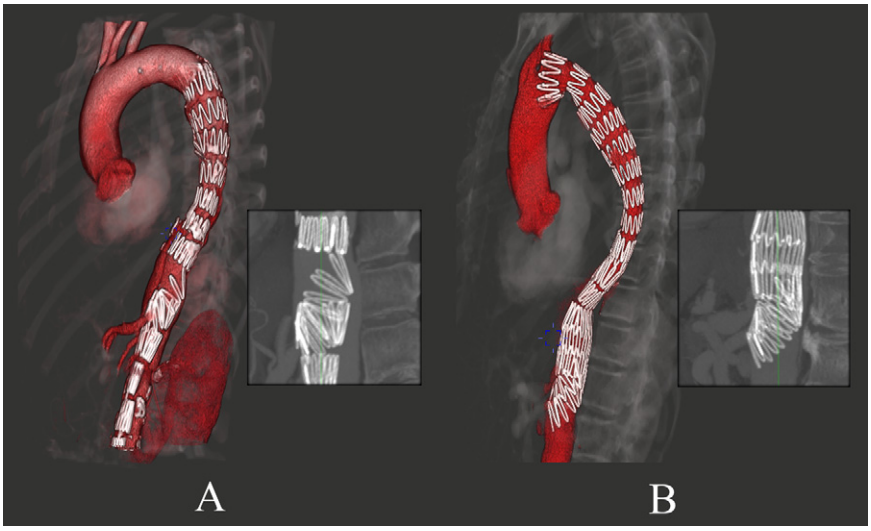

Fig 1. Postoperative computed tomography (CT) scan after deployment of the Zenith Dissection Endovascular System (ZDES) showing misalignment of the bare stent. **A,** Misalignment of the proximal bare stent (one case). **B,** Misalignment of the distal bare stent (four cases).

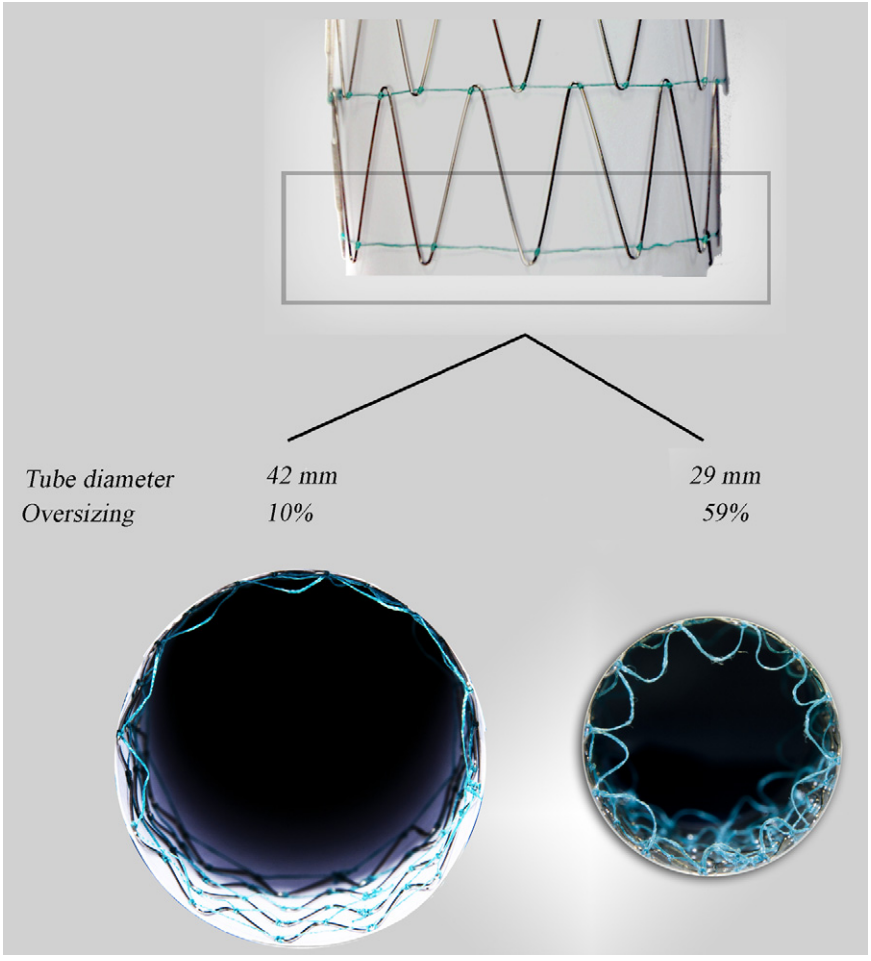

Fig 2. The Zenith Dissection Endovascular System (ZDES) released on various diameter plastic models. This figure demonstrates how the circumferential suture (*) may protrude into the aortic lumen if deployed in small-diameter vessels.

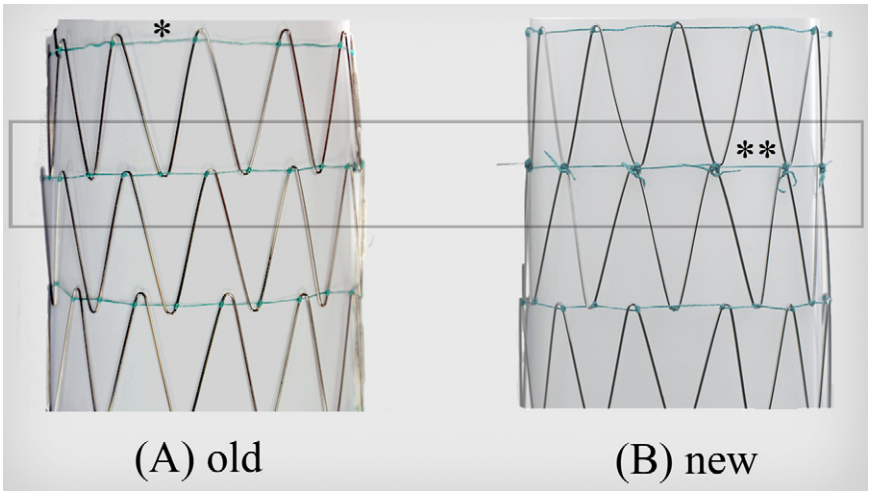

Fig 3. This pictures illustrates the distal (or proximal) end of the Zenith Dissection Endovascular System (ZDES). **A,** The steel Cook-Z stent segments are sewn together with a circumferential suture (*) with a peak-to-valley configuration in the old design. The new design involves the last two stents of both the proximal and distal end. **B,** A new suture has been added between each peak of the Cook-Z stent segments (**) of the first and second stent of the proximal and distal end to configure them in a peak-to-peak design.

further intervention for stent misalignment deemed necessary. No obstruction of aortic flow has been detected and no aortic side branch occlusion has been observed.

DISCUSSION

We have detected postoperative stent misalignment in four out of 25 patients with TBD treated with the ZDES.[5] We identified two possible mechanisms that may lead to this complication. The edges of the proximal and distal stent are constrained by metal wires that tether the bare stent to the central core of the delivery system during the deployment. We speculate that excessive movement of the device before trigger wire removal may result in misalignment. Analyzing the behavior of the ZEDS on a static model, particularly in a case of oversizing of the stent graft in a collapsed true lumen (range, 5 to 14 mm), we noticed an unfavorable behavior of the circumferential sutures (Fig 2): several loops protrude into the aortic lumen that may be engaged during endovascular manipulation at the end of the procedure or in cases of adjunctive/secondary interventions. The operator should be aware that these radiolucent loops may be inadvertently engaged by guidewires or other devices. Hydrophilic catheters and wires may help to avoid this problem.

The manufacturer has since modified the device, and the new version will be released on the market (Fig 3). This new configuration is intended to improve the apposition to the aortic wall by improving the columnar support of the proximal and distal end of the stent, thus avoiding misalignment during deployment or during inadvertent engagement of the distal loops.

Despite the absence of observed clinical consequences, this word of caution is appropriate during deployment of ZDES due to the possibility of creating stent misalignment. Careful review of postoperative images should be performed to detect this problem, and strict surveillance for potential complications seems warranted.

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